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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/628,225	07/28/2000	William W. Bachovchin	TUU-P01-006	3405

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EXAMINER	
RUSSEL, JEFFREY E	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 05/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/628,225	BACHOVCHIN ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 22 April 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☒ The proposed amendment(s) will not be entered because:

   (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See attachment*.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See attachment*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☒ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: *None*.

   Claim(s) objected to: *None*.

   Claim(s) rejected: *38-42 and 46-68*.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

1. The proposed new limitation requiring amounts sufficient to modify glucose metabolism but not sufficient to suppress the immune system of the animal would require further search of the prior art as to what is known concerning the immunosuppressive dosages of DPIV inhibitors and how they compare to dosages of DPIV inhibitors used to treat glucose intolerant animals or animals with diabetes. This limitation has not been searched or considered during previous prosecution of this application.

2. The proposed amendment to the specification would have overcome the objection set forth in section 1 of the final Office action.

3. The rejection under 35 U.S.C. 112, first paragraph, set forth in section 3 of the final Office action will be maintained, except that the two sentences starting with "However, the examiner has not" and ending with "as occurring in 1997.)" will be deleted. The article discloses only mice having a disrupted receptor gene. This specific disclosure does not support the genus of any animal having the receptor gene deleted or disrupted.

4. The proposed amendments to the claims would have overcome the objections set forth in section 4 of the final Office action.

5. The provisional obviousness-type double patenting rejections set forth in sections 6 and 7 of the final Office action will be maintained, even should the proposed new limitation discussed in section 1 above eventually be entered.

6. The claims would still be entitled under 35 U.S.C. 119(e) to the benefit of the filing date of provisional application 60/073,409 even should the proposed new limitation discussed in section 1 above eventually be entered.

7. The declaration by Drucker under 37 CFR 1.131 filed April 22, 2004 is insufficient to antedate either the Balkan et al abstract or the German Patent '486. The declaration is not signed by all of the inventors of the claimed subject matter. See MPEP 715.04. The declaration does not allege that the acts relied upon to establish the date prior to the reference were carried out in this country or a NAFTA country or a WTO member country. See MPEP 715.07(c). Finally, it appears that declaration is alleging that conception of the invention took place prior to the date of the Balkan et al abstract but that reduction to practice took place after the date of the Balkan et al abstract. This is uncertain because the declaration in section 3 indicates that conception took place prior to June 1997, but does not state how much prior to June 1997 the conception took place. Accordingly, it is not possible to determine whether the 6-month period of activity discussed in section 4 of the declaration concluded prior to or after the date of the Balkan et al abstract. Assuming that the 6-month period concluded after the date of the Balkan et al abstract, it is necessary for declarant to show evidence of facts establishing diligence between the time of conception and the time of actual reduction to practice. See MPEP 715.07(a). The declaration does not account, either with affirmative acts or acceptable excuses, for the entire period during which diligence is required. See MPEP 2138.06. The declaration does not contain evidence of diligence of the type discussed and found acceptable in this section of the MPEP. This same requirement for a showing of diligence also appears to be necessary in order to antedate the German Patent '486, published October 30, 1997.

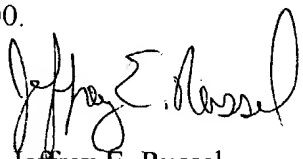
8. Concerning the obviousness rejection set forth in section 9 of the final Office action, assuming that the SDZ 272-070 of the Balkan et al abstract was a proprietary compound whose structure was not available at the time the invention was made, this does not vitiate the

obviousness rejection because the function of the compound is disclosed in the Balkan et al abstract, and the obviousness rejection is based upon the substitution of other compounds possessing the same function. The obviousness rejection does not allege that the Balkan et al abstract teaches the active agents required by instant claim 41, and does not allege that the Balkan et al abstract teaches oral administration. The WO Patent Application '259 does compensate for the deficiencies of the Balkan et al abstract because the WO Patent Application '259 suggests Applicants' claimed active agents and suggests their oral administration. Determining an optimal dosage schedule is not merely obvious to try, but is routinely performed in the pharmaceutical arts with a reasonable expectation of success. In general, one of ordinary skill in the art can administer known active agents in order to achieve their expected effects. Effendic et al is relevant to the rejected claims because it suggests that the active agents of the Balkan et al abstract and the WO Patent Application '259 can be used to treat Type II diabetes.

9. Concerning the anticipation rejection set forth in section 10 of the final Office action, the examiner maintains that Villhauer is enabling for the reasons of record. The examiner does not allege that column 9, line 66 - column 10, line 28 of Villhauer anticipates the instant claims.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback can be reached at (571) 272-0961. The fax number for formal communications to be entered into the record is (703) 872-9306; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

April 30, 2004